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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

CROSS, L

ART UNIT

PAPER NUMBER

1743

DATE MAILED:

02/14/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/473,165

Applicant(s)
Higuchi et al

Examiner
LaToya Cross

Group Art Unit
1743



☒ Responsive to communication(s) filed on Dec 28, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 6-13 is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 6-13 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☒ received in Application No. (Series Code/Serial Number) 08/959,125

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 10 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 contains the phrase "high molecular compound". It is unclear as to what Applicants intend by this phrase. Also, the term "high" is relative and thus indefinite.

Claim 13 contains the phrase "the polymer beads" and "the light reflective particles" which lack sufficient antecedent basis in the previous claim(s).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,589,347 to Arai et al (hereinafter Arai et al '347).

Applicants' invention is directed to a dry measuring test device comprising a reagent containing a chromogen in a matrix and a light blocking layer containing light blocking particles laminated on the reagent layer.

Arai et al '347 teach a multi-layer analysis element containing at least one hydrophilic polymer layer and a spreading layer on the hydrophilic layer. The hydrophilic layer contains colorimetric reagents and serves as the reagent layer (col. 3, lines 10-17). The multi-layer system also provides for a light-shielding (light-blocking) layer on the reagent layer. The light shielding layer contains light shielding particles such as carbon black (col. 4, lines 39-62).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated within the meaning of 35 USC 102e, in view of the teaching of Arai et al '347.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arai et al '347.

In addition to the teachings described above, Arai et al '347 further disclose that the light shielding layer is formed of fine particles (such as carbon black) dispersed in hydrophilic polymer binders such as polyvinyl alcohol (col. 3, lines 1-5 and col. 4, lines 39-47). At col. 5, lines 4-15, Arai et al '347 teach that the ratio of hydrophilic polymer binder to light-shielding particles is about 2.5-7.5 to 10. Arai et al '347 also disclose that single layers may be made to serve two or more functions (col. 3, lines 44-50).

Arai et al '347 differ from the instantly claimed invention in that the limitation of embedding the light-shielding particles in polymeric beads is not disclosed. However, Arai et al '347 disclose that light shielding particles are dispersed into a polymer and coated onto the reagent layer to dry. It is the position of the Examiner that the dispersion of light shielding particles into the polymer is equivalent to embedding the particles in polymers, absent evidence to the contrary. Applicants state at page 34, lines 20-25 of the instant specification, that light blocking particles embedded into polymeric beads are commercially available. Thus, absent evidence of unexpected results in using "embedded" particles over "dispersed" particles, it is submitted that one of ordinary skill in the art would consider both to be equivalent and it would be obvious to choose either in preparing the multi-layer test system.

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Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be obvious within meaning of 35 USC 103 in view of the teachings of Arai et al '347.

Citation of Relevant Prior Art

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is (703) 305-7360. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached at (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

LIC *sw*
February 7, 2001

Jill Warden
Jill Warden
Supervisory Patent Examiner
Technology Center 1700